

Supplemental Restriction/Election Requirement

1. The amendment filed on February 21, 2008 was not consistent with the restriction requirement the examiner believed he had made. (See attached interview summary). In order to clarify the restriction requirement, applicant is given the same restriction requirement again with the same Figure 1, however this time the definition of R_5 and R_6 phrased in the alternative. The source of the problem was the definition of the variables R_5 and R_6 . Please note that in addition to the group election an election of a single disclosed species is required. The claims of August 16, 2007 are being restricted and the claims submitted February 21, 2008 will not be entered.

Claims 1-13, 17-18 are pending as of the claim set of August 16, 2007.

Election/Restriction

Restriction is required under 35 U.S.C. 121 and 372.

2. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 1, 3-9, 12 & 18 drawn to compounds and compositions possessing a benzothiazepine core where in applicant's Markush structure of Formula I M^1 is CH_2 , M^2 is NR^{24} , R^1 and R^2 are H or lower alkyl, $R^4=R^7=R^9=R^8=R^{14}=R^{15}=R^{24}=H$, one of R^5 or R^6 is H or SMe and the other is IA, Z is O, R^{10} is cyclohexyl or phenyl, $n=1$, $m=0$, R^{13} is IB $p=1$, $q=0$, R^{16} is OH, $r=3$, R^{17} is C_{1-10} alkyl, said alkyl being ethyl and substituted with two R^{47} 's (one on each carbon), where both R^{47} 's are selected from hydroxy shown as structures **IA** and **IB** in Figure 1. If this group is elected, a single disclosed species is also required.

Group II, Claims 1-12, 14, 15, & 18 drawn to compounds and compositions possessing a benzothiepine core where in applicant's Markush structure of Formula I M^1 is CH_2 , M^2 is $CR^{22}R^{23}$, $R^{22}=OH$, R^1 and R^2 are H or lower alkyl, $R^4=R^7=R^9=R^8=R^{14}=R^{15}=R^{23}=H$, one of R^5 or R^6 is H and the other is IA, Z is S, R^{10} is cyclohexyl or phenyl, $n=1$, $m=0$, R_{13} is IB $p=1$, $q=0$, R_{16} is OH, $r=3$, R^{17} is C_{1-10} alkyl, said alkyl being ethyl and substituted with two R^{47} 's (one on

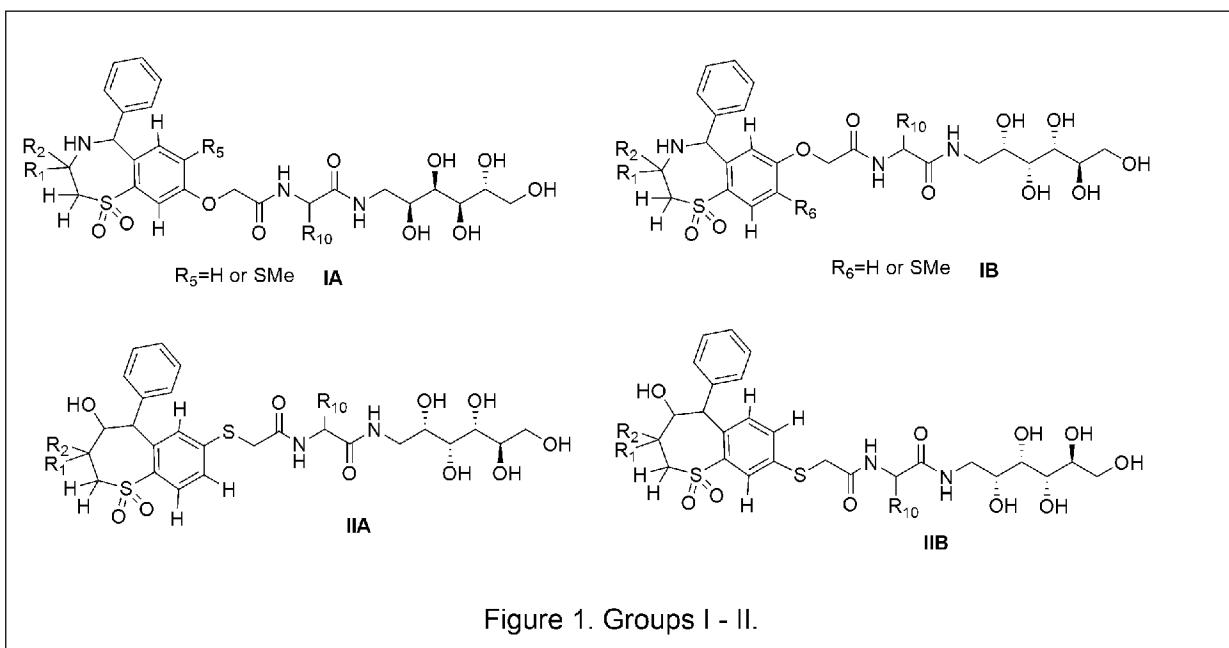
Art Unit: 1625

each carbon), where both R⁴⁷'s are selected from hydroxy shown as structure **IIA** and **IIB** in Figure 1, If this group is elected, a single disclosed species is also required.

Group III, Claims 1-9, 14, 15, & 18 drawn to compounds and compositions possessing a cores other than those of Groups I or II If this group is elected, a single disclosed species is also required. Further restriction based on the election may be made.

Groups IV-VI, Claim 13 drawn to processes for the preparation of compounds limited in scope to one of the groups I-III. If this group is elected, a single disclosed species is also required. Further restriction based on the election may be made.

Groups VII-IX, Claims 17 drawn to methods of treatment with compounds of groups I-III limited in scope to one of the groups I-III. If this group is elected, a single disclosed species is also required. Further restriction based on the election may be made.



The inventions listed as Groups I- IX do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

(f) “Markush practice” The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding

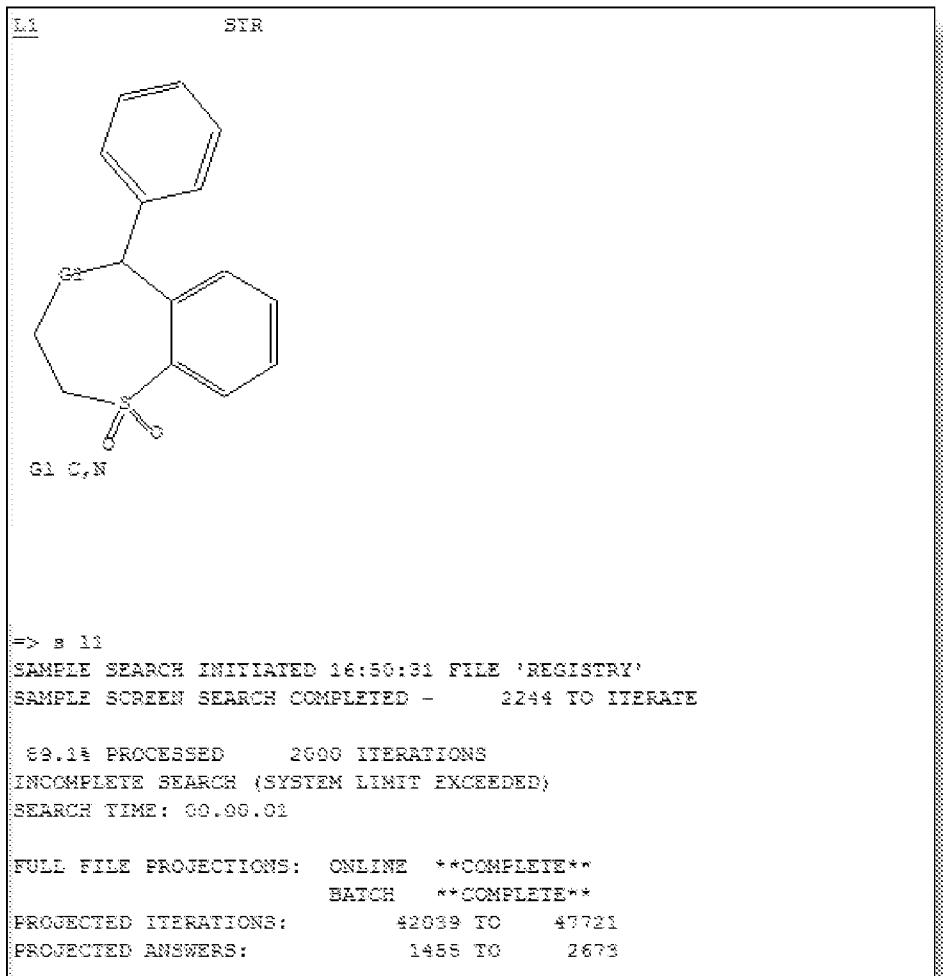
special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

(i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

- (A) All alternatives have a common property or activity; and
- (B) (1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or
- (B) (2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In paragraph (f)(i)(B)(1), above, the words “significant structural element is shared by all of the alternatives” refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The different variables M1, M2, Z, m, n, o, p, q, r and r R1-R67, etc. result in so many permutations giving both heterocyclic and non-hetero rings, different bonds between atoms, resulting in compounds that have achieved a different status in the art, and thus are drawn to an improper Markush group on the grounds of lack of a common nucleus. Thus lack of unity is apparent.

A preliminary search of a selected core gave numerous iterations, see below:



Thus it is clear that applicant's compound core is not applicant's contribution over the prior art and the commonly shared structure does not constitute a structurally distinctive portion in view of the existing prior art. Thus there is a lack of unity.

A prior art reference anticipating the claims with respect to one group would not render obvious the same claims with respect to another group. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP §821.041. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai; In re Brouwer and 35 U.S.C. §103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species and invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David K. O'Dell whose telephone number is (571) 272-9071. The examiner can normally be reached on Mon-Fri 7:30 A.M.-5:00 P.M EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Primary examiner, Rita Desai can be reached on (571)272-0684. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

D.K.O.

/Rita J. Desai/
Primary Examiner, Art Unit 1625